UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MALKA ASHKENAZI, individually, as Personal Representative of the Estate of the Decedent ELI ASHKENAZI, and HADAS ASHKENAZI (an adult child of the Decedent, all citizens of Israel),	:	
Plaintiffs,	:	
vs.	:	
BAYER CORPORATION, an Indiana corporation, successor to CUTTER BIOLOGICAL, a California corporation; BAXTER HEALTHCARE CORPORATION, a Delaware corporation, and its HYLAND DIVISION; BAXTER INTERNATIONAL, INC., a Delaware corporation, successor to IMMUNO - U.S., INC., a Michigan Corporation; ARMOUR PHARMACEUTICAL COMPANY, INC., a Delaware corporation, AVENTIS BEHRING LLC, a Delaware corporation, and AVENTIS INC., a Pennsylvania corporation; and ALPHA THERAPEUTIC CORPORATION, a California corporation,	:	Case No. 1:08-cv-01767 (Related to MDL No. 986 JFG)
Defendants.	:	Judge John F. Grady

DEFENDANT BAXTER HEALTHCARE CORPORATION'S ANSWER TO PLAINTIFFS' FIRST AMENDED COMPLAINT, AFFIRMATIVE DEFENSES AND DEMAND FOR JURY TRIAL

General Denial

Baxter Healthcare Corporation ("Baxter"), improperly identified in the Complaint and sued as Baxter Healthcare Corporation and its Hyland Division, by its undersigned attorneys,

denies that it is liable in any way to Plaintiffs based on the allegations in the Complaint. Baxter Healthcare Corporation states that to the extent this Complaint contains allegations directed to "Baxter/Immuno," "Immuno/Baxter," "Baxter International," "Immuno/Baxter International," "Immuno International A.G.," "Immuno - U.S." or any alleged entity other than Baxter Healthcare Corporation, either explicitly or otherwise, no answer is required by Baxter Healthcare Corporation. No response by Baxter Healthcare Corporation herein shall be deemed a response to allegations directed to "Baxter/Immuno," "Immuno/Baxter," "Baxter International," "Immuno/Baxter International," "Immuno International A.G.," "Immuno - U.S." or any other alleged entity. All references to "Baxter" in the Complaint shall be deemed to refer solely to Baxter Healthcare Corporation for purposes of this Answer. And, to the extent Baxter responds to allegations regarding Factor VIII and Factor IX concentrates, Baxter's responses shall be deemed to apply only to its Factor VIII and Factor IX concentrates and not to therapies processed by any other entity. Specifically, Baxter answers Plaintiffs' Complaint as follows:

I. ANSWER TO PLAINTIFFS' INTRODUCTION

1. Defendants manufactured blood products known as "Factor VIII" and "Factor IX" for the treatment of hemophilia, and sold these products to people with hemophilia in Israel and other foreign markets, despite knowledge that the products were manufactured from sick, high risk donors and/or known to be contaminated with the viruses that cause the Human Immunodeficiency Virus and Hepatitis C (now known as "HIV" or "HIV/AIDS" and "HCV" respectively). Defendants continued selling these products to people with hemophilia in Israel and elsewhere even after the products were no longer being used in the United States due to the known risk of HIV/AIDS and HCV transmission. As discussed more fully in paragraphs 66-69, Defendants, such as BAXTER/IMMUNO and CUTTER refused to recall old stocks of products they knew to be contaminated with HIV and HCV both in the United States and abroad even after they had introduced a safer product.

PARAGRAPH NO. 1 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits

only that it processed human plasma into Factor VIII and Factor IX concentrate used for the treatment of hemophilia. Baxter specifically denies that it engaged in any misconduct, denies that it "manufactured" Factor VIII or Factor IX, and denies that Factor VIII or Factor IX concentrates are blood "products." Baxter is without any knowledge or information as to facts alleged specifically regarding Plaintiffs and therefore denies them. The remaining factual allegations directed to Baxter, if any, are denied. Baxter is unaware of any entity known as "Baxter/Immuno" and makes no answer on behalf of such alleged "defendant."

2. Plaintiffs' decedent, ELI ASHKENAZI ("Decedent") had hemophilia, resided in Israel, and contracted HIV and HCV as a result of infusing Defendants' contaminated products. Further, Defendants, such as BAXTER/IMMUNO and CUTTER allowed their untreated factor concentrate products remain on the market in Israel for years after they were required to begin providing safer, treated factor concentrate products in the United States.

PARAGRAPH NO. 2 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter is unaware of any entity known as "Baxter/Immnuno" and makes no answer on behalf of such alleged "defendant."

3. Defendants manufactured HIV and HCV-contaminated blood factor products at plants in the United States using human plasma taken from thousands of paid American donors, including populations then known to be at high risk of carrying blood-borne diseases, such as urban homosexuals, prisoners, and intravenous drug users. Defendants intentionally recruited urban homosexuals who had a history of viral hepatitis as plasma donors, despite regulations prohibiting the use of such donors and despite knowledge that the viruses that cause HIV/AIDS and HCV were blood-borne diseases prevalent in such populations. Defendants continued using plasma taken from high risk prison donors, including from prisoners at the notorious Angola prison in Louisiana, even after promising the FDA that they would cease doing so. Through their trade associations, Defendants actively conspired to conceal these practices and to substantially delay product recalls and implementation of safety measures.

PARAGRAPH NO. 3 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is

required. To the extent that these allegations are factual and directed to Baxter, Baxter admits only that it processed factor concentrates from pooled plasma. Baxter denies that it "manufactured" Factor VIII or Factor IX concentrates, or that Factor VIII or Factor IX concentrates are blood "products." By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge. The remaining factual allegations directed to Baxter, if any, are denied.

4. Defendants failed to fully and completely disclose the known risks of their products, including the risk of HIV/AIDS and HCV, failed to implement readily available screening tests that would have prevented HIV/AIDS and HCV by excluding contaminated plasma; failed to use available methods of treating plasma to kill viruses, including heat treatment and solvent detergent; and concealed and affirmatively misrepresented the extent of the health dangers of the diseases caused by the products. Defendants continued to ship non-heat treated product to Israel and other foreign markets even after ceasing to sell it in the United States, in order to maintain their profit margin on existing contracts and sell off remaining stock no longer marketable domestically. Defendants also continued to sell old stocks of product that had not been treated with solvent detergent both in the United States and abroad, even after introducing a safer product treated with solvent detergent, including stocks that Defendants knew or had reason to know were made from pooled blood contaminated with HIV and HCV.

PARAGRAPH NO. 4 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter denies that Factor VIII or Factor IX concentrates are "products." The remaining factual allegations directed to Baxter, if any, are denied.

5. Defendants' efforts to maximize profits came at the expense of the health and lives of thousands of people with hemophilia in Israel and elsewhere who were needlessly infected with HIV/AIDS and HCV, including Plaintiffs' Decedent in Israel.

PARAGRAPH NO. 5 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is

required. To the extent that these allegations are factual and directed to Baxter, Baxter states that hepatitis transmission was a known risk associated with the use of factor concentrate and all Baxter factor concentrates carried an FDA approved hepatitis warning. The remaining factual allegations directed to Baxter, if any, are denied.

II. ANSWER TO ALLEGATIONS REGARDING JURISDICTION AND VENUE

6. Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between the Plaintiffs and the Defendants.

PARAGRAPH NO. 6 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required.

7. Pursuant to this Court's prior Order (attached hereto as **Exhibit A**), this action should be administratively transferred to MDL 986, pending before the Honorable John F. Grady, since it involves allegations of injuries and damages including HIV, HCV and related complications and injuries as a result of exposure to Defendants' blood factor products.

PARAGRAPH NO. 7 ANSWER: Baxter agrees that this action should be administratively transferred to MDL 986. The remaining factual allegations directed to Baxter, if any, are denied.

8. Plaintiffs are informed and believe and upon such information and belief allege that the unlawful, negligent and/or tortious activity alleged herein was carried out predominantly in the United States. Defendants recruited high risk paid donors in the United States and mixed plasma from such donors into the blood pool at their facilities in the United States. Defendants placed misleading labels on their products in the United States and made affirmative misrepresentations regarding their products' safety in the United States, which were relied upon by Plaintiffs and their medical providers. Defendants' decisions to recruit paid donors from high risk populations, to refrain from disclosing the known risks of their products, to forego implementing readily available procedures that would have prevented their products from transmitting HIV/AIDS and HCV, and to ship their products to Israel and other foreign markets even after they could no longer be used domestically were all made in the United States. Defendants' acts of conspiracy, including trade association meetings where they agreed to engage in wrongful conduct, also took place in the United States.

PARAGRAPH NO. 8 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that it engaged in unlawful, negligent or tortious activity, or that it engaged in a conspiracy or wrongful conduct.

9. Plaintiffs are informed and believe and upon such information and belief allege that the vast majority of the evidence of the unlawful activity alleged herein is located in the United States. Documents showing Defendants' policies, practices, and decisions regarding recruitment of plasma donors, mixing of plasma into the blood pool at their facilities, labeling of their products, advertising and promotion of their products, disclosure or lack thereof of the risks posed by their products, implementation or lack thereof of procedures to prevent their products from transmitting HIV/AIDS and HCV, and shipment of their products to Israel and other foreign markets are located almost exclusively in the United States. The vast majority of witnesses who will testify to these policies, practices, and decisions are also located in the United States, and would not be subject to subpoena in other countries. The expert witnesses likely to be presented by both Plaintiffs and Defendants are also located in the United States.

PARAGRAPH NO. 9 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that it engaged in any unlawful activity.

10. Most of the relevant medical records regarding the claims of Plaintiffs are located in the United States or have already been brought to the United States and have already been produced to Defendants. Similarly, Plaintiffs have produced or is in the process of preparing for production in the United States a Preliminary Patient Profile Form ("PPFs"). In addition, witnesses to the Plaintiffs' damages, such as the Plaintiffs' family members, are willing to travel to the United States to testify.

PARAGRAPH NO. 10 ANSWER: Baxter admits that it has received a PPF for Plaintiff's Decedent, Eli Ashkenazi. Baxter is without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the location of Plaintiffs' medical records and the

willingness of witnesses to travel to the United States and therefore denies them. The remaining factual allegations directed to Baxter, if any, are denied.

11. Because the Plaintiffs in this action reside in Israel with a different legal system, litigation in their home country would be costly and inefficient. In addition, Israel is an inadequate alternative forum because of chronic and lengthy court delays, lack of open discovery, unavailability of legal theories, procedures, and remedies, and lack of subpoena power over physical evidence in the United States.

PARAGRAPH NO. 11 ANSWER: The allegations of this paragraph constitute legal conclusions with respect to which no response is required. To the extent that this paragraph is deemed to include factual allegations, Baxter is without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

12. Plaintiffs are informed and believe and upon such information and belief allege that Defendants' unlawful activity was carried out largely in the United States, and, in significant part, in the Northern District of Illinois. Defendant ARMOUR PHARMACEUTICAL COMPANY had its only blood factor manufacturing and processing plant in Kankakee, Illinois, at all pertinent times. This plant was the location of many meetings regarding the processing and research and development of factor concentrates, including meetings in the early 1980s involving discussions about the possible use of solvent detergents in the manufacturing of blood factor concentrates. This plant was also the location of inspections by the United States Food and Drug Administration and Canadian authorities amid reports of viral infections being spread through the use of factor concentrates. In addition, at all times pertinent, ARMOUR PHARMACEUTICAL COMPANY had subsidiary Collection Centers, collecting blood from paid donors, in Illinois.

PARAGRAPH NO. 12 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that it engaged in any unlawful activity.

13. Defendants BAXTER HEALTHCARE CORPORATION ("BAXTER HEALTHCARE"), BAXTER INTERNATIONAL, INC. ("BAXTER INTERNATIONAL") and IMMUNO U.S. Inc. ("IMMUNO U.S.") had their headquarters in Illinois at all pertinent times.

Defendant BAXTER HEALTHCARE also collected blood from donors in Illinois at all times pertinent, including from donors jailed in the Cook County Jail in the early 1980s.

PARAGRAPH NO. 13 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that this paragraph includes factual allegations directed to Baxter, Baxter admits that it had its headquarters in Illinois. The remaining factual allegations directed to Baxter, if any, are denied.

14. Plaintiffs are informed and believe and upon such information and belief allege that considerable evidence of Defendants' unlawful activity is located, in significant part, in the Northern District of Illinois, where much of the unlawful activity was carried out.

PARAGRAPH NO. 14 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required from Baxter. Baxter specifically denies that it engaged in unlawful activity. The remaining factual allegations directed to Baxter, if any, are denied.

15. Plaintiffs are informed and believe and on such information and belief allege that the conduct by Defendants that is relevant to the subject matter of this action took place primarily in their respective headquarters locations, or in other facilities within the States of Illinois and California giving these states significant contacts to the claims asserted by Plaintiffs and creating state interests, such that the choice of either or each of these states' laws to govern the adjudication of this action is neither arbitrary nor fundamentally unfair, and Plaintiffs hereby consent thereto.

PARAGRAPH NO. 15 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

III. ANSWER TO ALLEGATIONS REGARDING PARTIES

16. The Plaintiffs in this action are as follows:

PARAGRAPH NO. 16 ANSWER: This paragraph does not include an allegation directed to Baxter and therefore no response is required.

17. Plaintiff MALKA ASHKENAZI, the surviving spouse of Decedent Eli Ashkenazi, who was a resident of Ness Ziona, Israel, and who had hemophilia, and who was infected with HIV and HCV as a result of infusing Defendants' contaminated factor concentrate and/or as a result of Defendants' conspiracy. Plaintiffs' Decedent has already provided Defendants with a confidential Preliminary' Patient Profile Form (PPF) with beginning Bates number L-PPF 00485; the PPF contains substantial additional information regarding Plaintiffs' claim. Plaintiffs MALKA ASHKENAZI resides in and is a citizen of Israel.

18. Plaintiff MOTI ASHKENAZI is the minor child of the Decedent, and resides in and is a citizen of Israel. Plaintiff MALKA ASHKENAZI is the lawful Guardian of the minor Plaintiff MOTI ASHKENAZI.

19. Plaintiff HADAS ASHKENAZI is the adult child of the Decedent, and resides in and is a citizen of Israel.

20. The Plaintiffs' Decedent, Eli Ashkenazi, was the beloved husband and father of the Plaintiffs and died on or about March 31, 2007, in Israel, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy. The Decedent resided in and was a citizen of Israel.

21. Plaintiffs' Decedent contracted permanent injuries and diseases, including HIV/AIDS and HCV and associated symptoms and diseases, as a direct and proximate result of use of Defendants' blood products and Defendants' conspiracy.

PARAGRAPH NOS. 17-21 ANSWER: To the extent that the allegations of these paragraphs constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that it has received a PPF for Plaintiff's Decedent, Eli Ashkenazi. Baxter is otherwise without knowledge or information sufficient to form a belief as to the truth of the alleged facts relating to Plaintiffs' and Plaintiffs' Decedent's citizenship, country of residence, hemophilia treatments, medical condition, state of mind or other personal information, and therefore denies them. Baxter specifically denies that it engaged in any conspiracy and denies all remaining factual allegations directed to Baxter.

22. Plaintiffs' Decedent would not have chosen to be treated with Defendants' blood products had he known of or been informed by Defendants of the true risks of using those products or the nature of the sources of the blood products.

PARAGRAPH NO. 22 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

23. CUTTER, the predecessor of Miles, Inc., and Defendant BAYER, was a California corporation headquartered in Berkeley, California at all pertinent times. CUTTER was at all pertinent times a citizen of California. At all pertinent times CUTTER and its successors Miles, Inc. and BAYER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

24. Defendant BAYER, formerly Miles, Inc., is and was an Indiana corporation, authorized to do business in all 50 states and the District of Columbia. Miles, Inc. had its principal place of business operation in Elkhart, Indiana, while its successor BAYER has its principal place of business in Pennsylvania, with offices located at 100 Bayer Road, Pittsburgh, Pennsylvania 15205. Defendant BAYER, at all pertinent times, is and was a citizen of Indiana and Pennsylvania. At all pertinent times BAYER and its predecessors Miles, Inc., and CUTTER regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of anti-hemophilic factor (hereinafter referred to as "AHF") produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

PARAGRAPH NOS. 23-24 ANSWER: The allegations of these paragraphs are directed to parties other than Baxter and therefore no response is required.

25. Defendant BAXTER HEALTHCARE is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, had its main manufacturing plant in Glendale, California. Defendant BAXTER HEALTHCARE, at all

pertinent times, is and was a citizen of Delaware and Illinois. At all times pertinent, Defendant BAXTER HEALTHCARE, and/or its HYLAND DIVISION, and/or its wholly owned subsidiaries Travenol Laboratories and Fenwal Laboratories, regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

PARAGRAPH NO. 25 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that this paragraph includes factual allegations directed to Baxter, Baxter admits that it is a Delaware corporation, with its principal place of business in Deerfield, Illinois, and that it is licensed to do business in multiple states, including California. Baxter further admits that it currently maintains a processing facility in Los Angeles, California. Baxter further admits that it has, through its Hyland Division, been engaged in collecting plasma and processing and distributing AHF. The remaining factual allegations directed to Baxter, if any, are denied.

26. Defendant BAXTER INTERNATIONAL is a Delaware Corporation, and owner and successor in interest to Immuno International A.G., and IMMUNO-U.S. (described hereinafter collectively as, "IMMUNO"). BAXTER INTERNATIONAL has its principal place of business in Illinois, with offices located at One Baxter Parkway, Deerfield, Illinois 60015, and, on information and belief, is the party liable for the injuries resulting from infusion with Immuno factor concentrates during the relevant period. Defendant BAXTER INTERNATIONAL, at all pertinent times, is and was a citizen of Delaware and Illinois.

PARAGRAPH NO. 26 ANSWER: The allegations of this paragraph are directed to parties other than Baxter and therefore no response is required from Baxter. Baxter admits that Baxter International, Inc. is a Delaware Corporation that has its principal place of business in Illinois. Baxter specifically denies that "Baxter International" is the owner of and/or successor in interest to Immuno International A.G. and/or Immuno-U.S. and further denies that Baxter International is in any way liable in this matter. The remaining factual allegations directed to Baxter, if any, are denied.

27. In 1997, BAXTER INTERNATIONAL acquired all assets and liabilities of Immuno International A.G., an Austrian company that at all times pertinent sold AHF products to Israel and other foreign markets that were produced from human plasma derived from paid donors in the United States. Immuno International A.G. operated in the United States at all times pertinent through its wholly owned American subsidiary Immuno-U.S., located in Rochester, New York IMMUNO operated 15 processing centers in the United States in the 1980s, which collected plasma from high-risk donors for fractionation in plants located in Rochester, Michigan and Vienna, Austria. These products were then shipped all over the world, and contributed directly or indirectly to Plaintiffs' infection with HIV and HCV. IMMUNO's product names, Bebulin, Feiba, and Prothromplex, are now listed as BAXTER INTERNATIONAL products in the 2003 Registry of Factor Concentrates put out by the World Federation for Hemophilia.

PARAGRAPH NO. 27 ANSWER: The allegations of this paragraph are directed to parties other than Baxter and therefore no response is required from Baxter. Baxter admits that Baxter International, Inc. is a Delaware Corporation that has its principal place of business in Illinois. Baxter specifically denies that "Baxter International" is the owner of and/or successor in interest to Immuno International A.G. and/or Immuno-U.S. and further denies that Baxter International is in any way liable in this matter. The remaining factual allegations directed to Baxter, if any, are denied. Baxter makes no response regarding Immuno International A.G., and denies that it ever acquired all assets and liabilities of Immuno International A.G.

28. IMMUNO - U.S. was a Michigan corporation and was at all pertinent times a United States based operating subsidiary of Immuno International A.G. The most recent corporate filing for IMMUNO - U.S. is the 1998 certificate of merger filed by BAXTER, listing the principal place of business for the surviving entity as One Baxter Parkway, Deerfield, IL 60015, the same address for Defendants BAXTER INTERNATIONAL and BAXTER HEALTHCARE.

PARAGRAPH NO. 28 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that it maintains an office in Deerfield, Illinois. Upon information and belief, Baxter further admits that, at all times pertinent to the allegations of this Complaint, Immuno - U.S. was a Michigan Corporation and a subsidiary of Immuno International A.G., an Austrian Company

with no corporate relationship to Baxter International, Inc. or Baxter Healthcare Corporation. By way of further answer, this paragraph purports to reference a 1998 document. Baxter denies all allegations related to such document, to the extent they are inconsistent with the provisions of the actual document. All remaining factual allegations directed to Baxter, if any, are denied.

29. Defendant ARMOUR PHARMACEUTICAL COMPANY, INC., (described hereinafter as "ARMOUR"), is a Delaware corporation, authorized to do business in all 50 states and the District of Columbia, with its principal place of business in Pennsylvania, with offices located at 500 Arcola Road, P.O. Box 1200, Collegeville, Pennsylvania 19426-0107. Defendant ARMOUR, at all pertinent times, is and was a ctizen of Delaware and Pennsylvania, Defendant ARMOUR sold AHF products which were produced from human plasma derived from paid donors in the United States. ARMOUR regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs' Decedent was exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and/or HCV.

PARAGRAPH NO. 29 ANSWER: The allegations of this paragraph are directed to parties other than Baxter and therefore no response is required.

30. Defendant ALPHA THERAPEUTIC CORPORATION (hereinafter "ALPHA") is a California corporation authorized to do business in all 50 states and the District of Columbia, with its principal place of business in California, with offices at 5555 Valley Boulevard, Los Angeles, California 90032. Defendant ALPHA, at all pertinent times, is and was a citizen of California. At all times pertinent Defendant ALPHA has been regularly and systematically engaged in the harvesting and collection of human plasma and the processing, manufacturing, marketing, sales and distribution of AHF products produced from such plasma, to which Plaintiffs' were exposed and which contributed directly or indirectly to Plaintiffs' Decedent's infection with HIV and HCV.

PARAGRAPH NO. 30 ANSWER: The allegations of this paragraph are directed to parties other than Baxter and therefore no response is required.

31. Defendants BAYER, ARMOUR, BAXTER HEALTHCARE, BAXTER INTERNATIONAL, and ALPHA (herein collectively identified as "MANUFACTURERS" or "DEFENDANTS") acting on behalf of themselves and/or their predecessor and/or successor corporations, collected, harvested and/or processed human plasma and/or manufactured, marketed, sold and distributed factor concentrate products to Israel and other foreign markets

that were contaminated with HIV/AIDS and/or HCV. In the alternative, one or more of said Defendants participated in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution and sale of factor concentrate products to Israel and other foreign markets, or assumed, became or are responsible for the liabilities of the Defendants and their predecessor or successor corporations who did participate in the collection, harvesting and/or processing of human plasma and/or the manufacturing, marketing, distribution or sale of factor concentrate products to Israel and other foreign markets, without limitation thereto.

PARAGRAPH NO. 31 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter no response is required from Baxter. Baxter admits that it is, and has in the past been engaged in collecting plasma and processing and distributing AHF. The remaining factual allegations directed to Baxter, if any, are denied. Baxter makes no response on behalf of "Baxter International," or "Immuno" (which is not a defendant in this action) and all responses herein are made solely on behalf of Baxter Healthcare Corporation.

32. At all times herein mentioned, all Defendants and each of them, were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and that all Defendants and each of them, thereby ratified those actions.

PARAGRAPH NO. 32 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter is without knowledge or information sufficient to form a belief as to the vague and ambiguous term "actions," and therefore allegations based thereon are denied.

IV. ANSWER TO PLAINTIFFS' FACTUAL ALLEGATIONS

A. Answer to Allegations Regarding Hemophilia and Its Treatment

33. Hemophilia is an inherited condition that causes uncontrolled hemorrhaging or bleeding. Hemophilia results from a deficiency of blood components essential for coagulation. The most common form of the disease is hemophilia A, characterized by a lack of a blood protein known as Factor VIII, which affects approximately one in 10,000 males. Factor VIII is

commonly called "AHF," or anti-hemophilic factor. Hemophilia B is characterized by absence of another blood protein, known as Factor IX, affecting about one in 40,000 males. Von Willebrand's disease is an inherited hemorrhagic condition similar to hemophilia that affects both men and women. It is characterized by lack of both Factor VIII and another blood protein called von Willebrand's factor.

PARAGRAPH NO. 33 ANSWER: Baxter admits that hemophilia and von Willebrand's disease are inherited hemorrhagic conditions, the circumstances of which vary from individual to individual. This paragraph does not state allegations directed to Baxter, but rather recites medical facts and information. Baxter denies the statements herein to the extent they are inconsistent with the current state of medical and scientific knowledge.

34. The treatment of hemophilia and von Willebrand's disease involves intravenous introduction, called infusion, of the missing blood proteins required to stop bleeding. The two most prevalent forms of such treatment are cryoprecipitate, and factor concentrates. Factor concentrates are the product made by Defendants in this action. Cryoprecipitate is made by freezing plasma, the fluid component of circulating blood in which various proteins, including Factor VIII and Factor IX, are contained; thawing the frozen plasma; and isolating Factor VIII from the plasma through centrifugal concentration. Cryoprecipitate is an effective therapeutic agent for patients with hemophilia A. Hemophilia B has been effectively treated with the use of fresh frozen plasma containing Factor IX Cryoprecipitate and fresh frozen plasma are made from small numbers of donors, who are generally unpaid volunteers.

PARAGRAPH NO. 34 ANSWER: Baxter admits that hemophilia and von Willebrand's disease are inherited hemorrhagic conditions, the circumstances of which vary from individual to individual. Baxter further admits that it does and has in the past processed therapies known as factor concentrates. Baxter specifically denies that Factor VIII or Factor IX concentrates are "products." This paragraph does not state allegations directed to Baxter, but rather recites medical facts and information. Baxter further denies the statements herein to the extent they are inconsistent with the current state of medical and scientific knowledge and/or are inconsistent with the instructions for use which accompany particular therapies.

35. By contrast, Defendants in the late 1960s to early 1970s began to market factor concentrates, or AHF, which contained Factor VIII and Factor IX in higher concentrations than had been available in either cryoprecipitate or fresh-frozen plasma. To produce factor concentrates, Defendants mixed pools of plasma from five to twenty thousand donors at a time, a substantial percentage of which were paid donors. These large pools were then subjected to chemical process to concentrate Factors VIII and IX.

PARAGRAPH NO. 35 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required from Baxter. Baxter admits only that it processes and distributes factor concentrates according to its own proprietary methods, from pooled plasma collected primarily from paid donors. The availability of factor concentrate therapies in the late 1960's and/or early 1970's marked a huge advance in the treatment of hemophilia. Baxter specifically denies that the term "AHF" refers to all factor concentrates or that "AHF" includes Factor IX. The remaining factual allegations directed to Baxter, if any, are denied.

B. Answer to Allegations Regarding Failure to Disclose or Warn

36. Shortly after the initial commercial marketing of Factor VIII and IX concentrates in the late 1960s to early 1970s, a wide range of serious adverse effects were reported in association with these products. Even before the dissemination of HIV, Defendants knew of serious diseases caused by unidentified agents transmissible by blood and Factor VIII and IX. Defendants failed to warn Plaintiffs, Plaintiffs' Decedent or the medical community of these adverse effects, in violation of industry standards and federal regulations.

PARAGRAPH NO. 36 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

37. By 1976, only a few years after Defendants' factor concentrate products went on the market, the United States Food and Drug Administration ("FDA") Bureau of Biologics held a

conference entitled "Unsolved Therapeutic Problems in Hemophilia." The research articles compiled from the conference discussed the high incidence in patients using Defendants' products of disorders such as liver dysfunction, enlarged spleen, Hepatitis B, and Non-A, Non-B Hepatitis ("NANB Hepatitis," later renamed Hepatitis C). The articles concluded that these disorders were tied to the patients' use of factor concentrates, and emphasized the risks entailed in producing such concentrates using plasma from paid donors. As described below, however, Defendants not only refused to implement such a voluntary donor system, but instead recruited paid donors precisely because their hepatitis exposure resulted in plasma from which Defendants could make other commercially valuable products as well.

PARAGRAPH NO. 37 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference research articles published in the 1970s. Baxter denies such references to the extent they are inconsistent with the plain meaning of the writings themselves and denies Plaintiffs' characterization of the writings. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge. The remaining factual allegations directed to Baxter, if any, are denied.

38. Several of the articles from the 1976 conference also raised alarm over the unprecedented convergence of immune disorders in the hemophiliac community, and called for close medical monitoring of the situation.

PARAGRAPH NO. 38 ANSWER: This paragraph purports to reference research articles published in the 1970s. Baxter denies such references to the extent they are inconsistent with the plain meaning of the writings themselves and denies Plaintiffs' characterization of the writings.

39. At all times material to this Complaint, Defendants failed to adequately warn Plaintiffs, Plaintiffs' Decedent or his physicians of these serious adverse side effects. Several such adverse effects, including immunosuppression (suppression of the immune system) were not mentioned at all in the Defendants' package inserts, which were required to disclose adverse reactions pursuant to federal statutes and regulations and applicable standards of care. Although Defendants' inserts mentioned a risk that plasma "may" contain the causative agent of viral hepatitis, the warning was seriously deficient in that: (a) Defendants failed to disclose that the risk of hepatitis was essentially a 100% guarantee due to their practices of using high-risk donors

and specifically recruiting for donors who had previously been exposed to Hepatitis B; (b) while "hepatitis" simply means inflammation of the liver, and may be a relatively benign, temporary condition, Defendants failed to warn that some forms of hepatitis transmitted by their products were believed to present a considerable risk of severe liver damage, cirrhosis, and significantly elevated risk of cancer; (c) Defendants misleadingly stated that the source plasma used in preparation of the product had been found to be non-reactive for Hepatitis B surface antigen (HBsAg)—implying that no viral hepatitis was present in the plasma—and falsely stated that available methods were not sensitive enough to detect all units of potentially infectious plasma, while failing to disclose that Defendants had refused to implement the more sophisticated Hepatitis B Core Antibody (HBc) test which would have excluded essentially all plasma contaminated by Hepatitis B; and (d) Defendants' labeling disclosed that the product was made from large pools of fresh human plasma, but failed to disclose that paid donors increased the risk of disease, and that the particular groups of paid donors targeted by Defendants were known to be the highest risk groups available.

PARAGRAPH NO. 39 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations and acted in accordance with the existing state of medical and scientific knowledge. The remaining factual allegations directed to Baxter, if any, are denied.

C. Answer to Allegations Regarding Alleged Recruitment of Donors From High Risk Populations

40. The demand for and supply of anti-hemophilia factor rapidly increased during the 1970's, with the commercially-manufactured concentrate accounting for a large proportion of the increase in supply. In 1977, a federal report projected that the volume of AHF manufactured would increase substantially by 1980. ("Study to Evaluate the Supply-Demand Relationships for AHF and PTC Through 1980," Division of Blood Diseases and Resources, National Heart, Lung and Blood Institute (1977), at page 8; hereinafter "NHLBI Report").

PARAGRAPH NO. 40 ANSWER: This paragraph does not allege any facts directed to Baxter but rather purports to reference and quote a specific report. Baxter denies the allegations of this paragraph to the extent they are inconsistent with the plain meaning of the referenced report.

41. In order to sell more AHF to this growing market, Defendants turned to the fastest and cheapest way of obtaining sufficient plasma, paid donors. Defendants recruited paid donors from those populations most likely to respond to the financial incentive to donate: poor inner city residents, drug abusers, prisoners, and even residents of impoverished developing countries such as Haiti and Nicaragua.

PARAGRAPH NO. 41 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

42. Defendants purposefully sought out paid donors despite knowing that the risk of diseases transmissible by blood was far greater among paid donors than among volunteers. Because no test was available yet for the NANB Hepatitis virus identified in the early 1970's, the only means to prevent the virus from contaminating the plasma supply was to exclude donors with behaviors that were inconsistent with good health—precisely those populations from which Defendants were recruiting paid donors. Some studies indicated that paid donors were up to ten times more infectious than volunteer donors. For this reason, the National Blood Policy, adopted by the federal government in July 1973, advocated conversion to an all-volunteer blood supply. Defendants, however, not only continued to use paid donors, but also focused their recruiting efforts on the highest risk populations.

PARAGRAPH NO. 42 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference various studies and reports. Baxter denies such references to the extent they are inconsistent with the plain meaning of the documents. The remaining factual allegations directed to Baxter, if any, are denied.

43. Defendants had an additional financial incentive for recruiting paid donors. Factor VIII and Factor IX are only two of many products that can be made for commercial sale from human plasma. According to the NHLBI Report, by the late 1970s at least 17 different therapeutic components of blood were manufactured by the process of "fractionating" plasma into its various elements. The NHLBI Report noted that, "as the costs of fractionation have increased, fractionators have produced as many products as possible from a liter of plasma." (Id. at 65).

PARAGRAPH NO. 43 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is

required. This paragraph purports to reference and quote a specific report. Baxter denies such references to the extent they are inconsistent with the plain meaning of the report. Baxter admits that plasma is a scarce resource and that Baxter made an effort not to waste this valuable resource that can be processed into various therapeutic applications. The remaining factual allegations directed to Baxter, if any, are denied.

44. Blood derivatives used as vaccines or therapeutics had particularly high economic value for Defendants. The NHLBI Report noted that plasma with a very high titer, or antibody level, for a corresponding antigen is "very expensive." (Id. at 41). Such products are manufactured from source plasma drawn from donors who have been sensitized to a particular antigen. (Id.). The NHLBI Report specifically stated, however, that "plasma collected for high antibody titer cannot be used for fractionation into therapeutic products," such as Defendants' factor concentrate. (Id., emphasis added).

PARAGRAPH NO. 44 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference and quote a specific report the accuracy and authenticity of which is not known to Baxter and Baxter therefore denies the allegations regarding such report. The remaining factual allegations directed to Baxter, if any, are denied.

45. Defendants targeted donors with high titers to Hepatitis B antigens in order to manufacture and sell Hepatitis B immunoglobulin (HBIG), a product that confers temporary immunity to the Hepatitis B virus. Despite the warning in the NHLBI report, Defendants' used the same high titer plasma they obtained for making HBIG to manufacture the Factor VIII and IX products used by people with hemophilia. Defendants thus sought to maximize profits by producing "as many products as possible from a liter of plasma," while ignoring industry standards that precluded the use of high-titer plasma for other therapeutic products.

PARAGRAPH NO. 45 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that high titer plasma is used to make hepatitis B immune globulin and

that certain donors with the necessary high titers were sought for that purpose. The remaining factual allegations directed to Baxter, if any, are denied.

46. Beginning in about 1978, Defendants BAXTER, CUTTER and ALPHA began targeting homosexual donors in known urban gay communities. Because urban homosexuals had been reported in the 1970's to have exceptionally high prevalence of Hepatitis B infection, Defendants knew that such donors would provide a reliable source of plasma for the manufacture of commercially valuable HBIG.

PARAGRAPH NO. 46 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

47. It was also well-known in the public health community by the 1970's that urban homosexuals engaged in promiscuous sexual practices that rapidly transmitted other diseases, including NANB Hepatitis, which were transmitted by blood, could not be isolated nor identified, and were believed to have serious adverse consequences. Despite this knowledge, Defendants used the same plasma pool from urban homosexuals to manufacture both HBIG and Factor VIII and IX.

PARAGRAPH NO. 47 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

48. Defendants continued this dual use of high risk plasma even after federal reports warned of the rapid spread of fatal immunosuppressive disease among the same homosexual population from which Defendants heavily recruited. Defendants knew or should have known by no later than the summer of 1981 that urban homosexual males were not "suitable donors" within the meaning of federal regulations and/or other applicable standards of care.

PARAGRAPH NO. 48 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

49. By the 1970s, it was also well-established that plasma from prison populations carried a high risk of hepatitis and other blood-borne diseases, primarily because of the concentration of intravenous (IV) drug users in prisons. Despite knowledge of this risk, Defendants actively recruited prisoners for plasma used to manufacture Factor VIII and IX, while concealing or failing to disclose the risk to Plaintiffs, Plaintiffs' Decedent, his physicians, or the FDA.

PARAGRAPH NO. 49 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

50. In light of Defendants' special knowledge of the disease patterns among urban homosexuals and prisoners, and their recruitment of such donors for Factor VIII and IX manufacture, Defendants had duties to: (a) promptly investigate the first reports of opportunistic infections among urban homosexuals in 1981; (b) discontinue the practice of using such high risk donors; (c) disclose the risk to Plaintiffs, Plaintiffs' Decedent, his physicians, and the FDA, including the ongoing risk of continuing to use Factor VIII and IX previously manufactured with high risk plasma and still marketed to patients; (d) implement procedures to kill blood-borne diseases in the products; and (e) recall existing products from distribution or further use. Instead, Defendants continued to conceal their recruitment of high risk donors and resist warnings and recalls, and failed to implement procedures to make their products safe.

PARAGRAPH NO. 50 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies "concealing" anything.

D. Answer to Plaintiffs' Allegation Regarding HBc Testing

51. By no later than 1978, Defendants knew of the availability of a new test to determine whether an individual had a history of viral Hepatitis, which would have disqualified the donor from providing plasma for the manufacture of Factor VIII or IX. By testing a person's serum for the presence of the core to the Hepatitis B antibody, a history of viral Hepatitis could be verified. This was known as the "HBc test." Published, peer-reviewed literature shows that the HBc test was in use by researchers to determine that homosexual AIDS victims had a history

of viral Hepatitis by no later than December 1981. (Gottlieb, et al., "Pneumocystis Carinii Pneumonia and Mucosal Candidiasis in Previously Healthy Homosexual Men," NEW ENGLAND JOURNAL OF MEDICINE 1981; 305:1425-1431).

PARAGRAPH NO. 51 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

52. Use of the HBc test would have eliminated approximately 75% of homosexual plasma donors and over 90% of promiscuous urban homosexuals. It would have eliminated almost 100% of intravenous drug users.

PARAGRAPH NO. 52 ANSWER: The allegations of this paragraph are denied.

53. Use of the HBc and ALT tests by Defendants by 1981 would have eliminated the vast majority of the transmitters of HIV and HCV from the blood and plasma pools of the nation, before the height of the AIDS and Hepatitis C epidemics. If Defendants had implemented this test in a timely manner, Plaintiffs' Decedent would never have been infected with HIV or HCV as a result of factor concentrate use.

PARAGRAPH NO. 53 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

54. Plaintiffs' Decedent and thousands of other people with hemophilia in Israel and other countries became infected by the AIDS and Hepatitis C viruses through repeated exposures from blood products manufactured from large pools of plasma donors (5,000 to 40,000). If Defendants had used the HBc and ALT tests to decrease by 70% to 90% the number of HIV and HCV positive donors who went into a pool, the infectivity of the product would have decreased substantially. Consequently, the rate of infection of people with hemophilia would have slowed down enormously, and the medical and scientific community would have been given more time to react appropriately to the HIV and Hepatitis C epidemics.

PARAGRAPH NO. 54 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter is without knowledge or information sufficient to form a belief as to the source

of Plaintiffs' and other alleged hemophiliacs' "AIDS" and Hepatitis C infections and therefore denies such allegations. The remaining factual allegations directed to Baxter, if any, are denied.

55. As noted below, federal regulations required plasma donors to be in good health, and donors with a "history of viral Hepatitis" were by definition unacceptable as blood or blood plasma donors. Persons with a history of viral hepatitis were excluded not only because of the risk of transmitting Hepatitis B, but because such a history indicated a lifestyle or previous behavior of the prospective donor which carried the risk of transmitting other viruses in addition to hepatitis. A reasonable and prudent plasma fractionator would not accept a HBc positive donor and expect to be in compliance with federal regulations as of 1978.

PARAGRAPH NO. 55 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. By way of further response, this paragraph purports to reference and interpret federal regulations. Baxter denies every allegation inconsistent with the plain language of the regulations as applied and interpreted by the FDA during the relevant period. The remaining factual allegations directed to Baxter, if any, are denied.

56. After public reports of the first hemophilia AIDS cases in July 1982, government officials urged Defendants to implement the HBc test as a "surrogate" or "marker" to eliminate plasma contaminated by the transmitter of AIDS or Hepatitis C. HBc testing was also strongly suggested to Defendants by the CDC at a meeting of the United States Public Health Service ("PHS") on January 4, 1983. Despite this urging, Defendants continued to use contaminated plasma donations that would have been excluded by the HBc test and continued to conceal from Plaintiffs, Plaintiffs' Decedent, his physicians, and the FDA the dangerous practice of targeting donors at highest risk for the very diseases that disqualified their plasma. At a January 6, 1983 meeting of Defendants' trade association, the Pharmaceutical Manufacturer's Association, Defendants agreed not to implement the highly effective HBc donor screening, and instead opted to use ineffective donor questionnaires that did little to screen out donors at high risk for AIDS and Hepatitis C transmission.

PARAGRAPH NO. 56 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of

further answer, Baxter specifically denies that HBc testing was "highly effective" for screening donors.

57. As late as December 13, 1983, years after the HBc test was available, a memorandum from CUTTER's responsible head Stephen Ojala to various CUTTER executives, reporting back on a meeting held by all Defendants, shows that all Defendants conspired to propose a "task force" to further study the use of HBc as an intentional, bad faith "delaying tactic for the implementation" of the test.

PARAGRAPH NO. 57 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies that it ever conspired with anyone to do anything. Baxter further explicitly denies that it participated in any "delaying tactic" and further denies that it participated in the preparation of any other defendant's internal documents or adopted the representations in such documents as its own.

E. Answer to Plaintiffs' Allegations Regarding Heat Treatment and Solvent Detergent

58. In the late 1970s and early 1980s, it was recognized that viruses were in all AHF products, including Factor VIII and IX. Heat treatment and solvent detergent was available at that time to eliminate many of these viruses, including HIV and HCV. Defendants were required to take reasonable steps to eliminate contamination, but Defendants failed to utilize these available technologies to eliminate the viruses in a timely manner.

PARAGRAPH NO. 58 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that in the late 1970's and early 1980's hepatitis was recognized as the sole known viral pathogen transmissible via Factor VIII and Factor IX. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care,

complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

59. The 1977 NHLBI Report noted that albumin, another plasma product, was "heat treated to remove almost all danger of hepatitis." (Id., at p. 49). Defendant ARMOUR'S memorandum of June 1983 acknowledged that no cases of AIDS had been reported in heat--treated albumin users, but misleadingly states that heat treatment of Factor VIII and IX was not yet feasible. It was clearly known by no later than 1977 that heat treatment was an effective way to make blood products safer, but Defendants wrongfully refused to implement such procedures as to Factor VIII and IX. In 1995, the National Institutes of Health Institute of Medicine ("IOM") issued a report on the hemophilia AIDS epidemic which concluded that defendants "did not seriously consider alternative inactivation processes," including heat treatment, and that "heat treatment processes to prevent the transmission of hepatitis could have been developed before 1980." Heat treated, HIV-safe factor concentrates were not introduced by any Defendant until 1983, and were not universally in use until 1985.

PARAGRAPH NO. 59 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. This paragraph purports to reference and quote various reports and documents the accuracy and authenticity of which are not known to Baxter and Baxter therefore denies the allegations related to them. Baxter admits that, unlike factor concentrate, albumin could be readily heated. Baxter further admits that its heat-treated factor concentrate was licensed in 1983. Baxter is without knowledge or information sufficient to form a belief as to when "HIV-safe" factor concentrates were "universally" used and therefore denies such allegations. The remaining factual allegations directed to Baxter, if any, are denied.

60. In addition to heat treatment, solvent detergent treatment was available to Defendants by the late 1970's as a simple and effective method of eliminating viruses in their factor concentrate products. Solvent detergent effectively kills viruses such as HIV and HCV by destroying the viruses' lipid envelope. It is simpler than heat treatment, and unlike heat treatment does not interfere with the Factor VIII and IX proteins needed for blood clotting.

PARAGRAPH NO. 60 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

61. Solvent detergents were well-known, commercially available products as of the 1970's, and studies in which solvent detergent treatment was used to disrupt viruses were published in the 1970's in peer-reviewed journals. In 1980, Dr. Edward Shanbrom, a former BAXTER scientist, received a patent for a solvent detergent treatment process for viral inactivation of factor concentrate. Dr. Shanbrom describes the implementation of this process as "as easy as washing your hands."

PARAGRAPH NO. 61 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter specifically denies that solvent detergents were well known or commercially available for use in factor concentrates in the 1970's or that peer review articles addressed solvent detergents in factor concentrates at that time. The remaining factual allegations directed to Baxter, if any, are denied.

62. After receiving the patent, Dr. Shanbrom approached various Defendants about implementing the solvent detergent method, but these Defendants wrongfully refused to implement the method. Several of the Defendants refused to even commit any resources to investigate the method. However, in June, 1985, the New York Blood Center ("NYBC") obtained a license from the FDA to implement the process for Factor VIII. The NYBC obtained a license to use the process in 1987. On information and belief, by 1987, all Defendants except ARMOUR were using the process to virally inactivate their Factor VIII blood products.

PARAGRAPH NO. 62 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies any wrongdoing.

63. Although heat treatment was effective in destroying the HIV virus, it was ineffective in destroying HCV and HBV. A recent CDC study reported that "84% of previously

untreated patients infused with dry-heated Factor VIII products developed non-A, non B hepatitis ... several case reports of probable transmission of HBV and HCV through vapor heat-treated and pasteurized products later appeared." (Risk Factor for Infection with HBV and HCV in a Large Cohort of Hemophiliac Males: Soucie, Richardson, Evatt et al; Transfusion, 2001; 41:338-343)

PARAGRAPH NO. 63 ANSWER: This paragraph does not include allegations directed to Baxter but rather purports to recite medical and scientific information. Baxter denies such statements to the extent they are inconsistent with the state of medical and scientific knowledge. This paragraph further purports to quote a published article, the accuracy and authenticity of which are not known to Baxter, and Baxter therefore denies such quotation and further denies Plaintiffs' characterization of the quotation.

64. The same CDC study reported that "solvent detergent treatment of blood components found to be more effective against enveloped viruses than heat treatment ... No cases of HBV, HCV, or HIV transmission through solvent detergent virus inactivated products have been found in prospective studies of previously untreated patients..."

65. The study further reported "in our data, the first dramatic decline in HCV prevalence appears in the 1987 birth cohort. The drop in HCV transmission correlates with the licensing of solvent detergent treatment of factor IX products in 1987. In addition, this cohort would have been the first to benefit from the screening of blood donors using the surrogate markers ALT (begun in late 1986) and anti-HBc (begun in 1987), testing that was associated with a markedly decreased risk of HCV infection from blood transfusions."

PARAGRAPH NOS. 64-65 ANSWER: These paragraphs do not include allegations directed to Baxter but rather purport to recite medical and scientific information. Baxter denies such statements to the extent they are inconsistent with the state of medical and scientific knowledge. These paragraphs further purport to quote a published article, the accuracy and authenticity of which are not known to Baxter, and Baxter therefore denies such quotations.

66. The study states further that "the residual transmissions after 1987 possibly represent the use of product already manufactured or product manufactured during the interval required to implement the new technology. The 18-month shelf life of factor concentrates placed those people with hemophilia born as late as 1989 at risk of infection." The study goes on to

recommend testing for all people with hemophilia who received infusions of the defendant's blood products prior to 1992.

PARAGRAPH NO. 66 ANSWER: This paragraph does not include allegations directed to Baxter but rather purports to recite medical and scientific information. Baxter denies such statements to the extent they are inconsistent with the state of medical and scientific knowledge. This paragraph further purports to quote a published article, the accuracy and authenticity of which are not known to Baxter, and Baxter therefore denies such quotation and further denies Plaintiffs' characterization of the quotation.

67. The failure of Defendants to implement solvent detergent viral inactivation techniques in a timely manner, to warn of the risk that heat treated Factor VIII and IX blood products could transmit HBV and HCV, and to recall heat treated products that posed this risk caused the needless infection of thousands of people with hemophilia with HCV and HBV after 1983, including Plaintiffs' Decedent. Even after Defendants knew or should have known that the solvent detergent process effectively destroyed HCV and HBV, as well as HIV, they continued to sell heat treated Factor VIII and IX, and refused to recall these dangerous products from the market.

PARAGRAPH NO. 67 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

F. Answer to Allegations Regarding Shipment of Non-Heat Treated Factor Concentrate Abroad

68. Between 1983 and 1985,Defendants stopped selling non-heat treated factor concentrate in the United States and introduced a vastly safer heat-treated version. However, one or more Defendants, including BAXTER (successor to IMMUNO) and BAYER (successor to CUTTER) continued to allow their remaining stocks of non-heat treated product to remain on the market in Israel and other countries after ceasing sales of such product in the United States, despite knowledge that the non-heat treated product was contaminated with HIV and/or HCV.

PARAGRAPH NO. 68 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is

required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter further denies that it is the owner of and/or successor in interest to Immuno International A.G. and/or Immuno-U.S. and denies that Baxter is in any way liable in this matter.

69. As detailed in this Complaint, by the end of 1982 Defendants' internal communications in the United States revealed their awareness of the AIDS risk posed by their products, but they continued to disavow the connection between AIDS and factor concentrates in their communications to foreign doctors and persons with hemophilia. In mid-1983, months after CUTTER executives authored internal memos expressing their belief that factor concentrates transmitted AIDS, the company wrote a letter to its foreign distributors, including one in Israel, in which it characterized the concern over AIDS as an "irrational response," and dismissed the notion that AIDS could be transmitted by factor concentrates as "unsubstantiated speculation." (Internal Defendant documents) CUTTER told the distributors that "[w]hat little evidence exists . . . tends to suggest that AHF concentrates have no direct role in [the AIDS] syndrome."

PARAGRAPH NO. 69 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to a party other than Baxter, no response is required. By way of further answer, this paragraph purports to reference certain unidentified internal documents. Baxter is without knowledge or information sufficient to form a belief as to the identity, accuracy or authenticity of these documents and therefore denies the allegations regarding them. The remaining factual allegations directed to Baxter, if any, are denied.

70. Even after Defendants introduced heat-treated products that did not transmit HIV and touted the safety of these new products, they continued selling their contaminated non-HT product abroad.

PARAGRAPH NO. 70 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter admits that its heat-treated Factor VIII concentrate was licensed in the United States in March of 1983 and that it continued to sell non-heat treated factor concentrate in the United States and ship it elsewhere for some period of time thereafter. Baxter denies the allegations regarding

continued sales in Israel to the extent they are inconsistent with documents produced by Baxter. The remaining factual allegations directed to Baxter, if any, are denied.

71. In October of 1984, the CDC issued a report announcing that 74% recipients of Factor VIII concentrates made from plasma derived from American donors were HIV positive. CDC data supports the role American factor played in spreading AIDS among Plaintiffs' Decedent and other persons with hemophilia in Israel. The CDC report also publicized studies showing that heat treatment effectively killed the HIV virus. Upon information and belief, Defendants did not upon receiving this news recall or withdraw their unheated products from Israel. Such products therefore remained on the shelves and continued infecting Israeli hemophiliacs until their expiration dates.

PARAGRAPH NO. 71 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. By way of further response, this paragraph purports to reference and interpret a purported CDC report. Baxter is without knowledge or information sufficient to form a belief as to the identity, accuracy and authenticity of such report and therefore denies the allegations regarding it. The remaining factual allegations directed to Baxter, if any, are denied.

G. Answer to Allegations of Misrepresentation and Fraudulent Concealment

72. Defendants engaged in a pattern and practice of fraudulent concealment of their dangerous practices, fraudulent misrepresentations of the extent of their efforts to assure safety, and fraudulent misrepresentations that understated the risk of AIDS and Hepatitis C, in order to maintain profits from both factor concentrates and HBIG. A summary of Defendants' fraudulent misrepresentations and concealment is set forth below.

PARAGRAPH NO. 72 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies misrepresenting or fraudulently concealing anything.

73. On July 27, 1982, a meeting of the Public Health Service was held as the result of the CDC's report of three people with hemophilia who contracted AIDS. The responsible heads

of ARMOUR, ALPHA, CUTTER and BAXTER HEALTHCARE were in attendance, along with officials from the National Hemophilia Foundation, CDC and FDA. At least three of the Defendants were aware that they had used cryoprecipitate containing plasma from known, targeted homosexuals in the manufacture of Factor VIII and IX blood products. These products had a shelf life of two and three years, respectively, and were either in production or already on the shelves in pharmacies waiting to be infused by people with hemophilia who purchased them. The Defendants involved, BAYER, BAXTER and ALPHA, failed to disclose these facts at the meeting where CDC officials Dr. Don Francis and Dr. Jeff Koplin were present, despite knowledge that the CDC's primary concern at that meeting was the infection of Factor VIII and IX by the transmitter of AIDS, which was already well-known to be epidemic in the targeted homosexual population. (CUTTER memorandum dated August 3, 1982)

PARAGRAPH NO. 73 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

74. In or about December, 1982, Rodell, the responsible head for BAXTER HEALTHCARE, entered into an agreement with officials of the FDA to the effect that BAXTER HEALTHCARE would no longer use prison plasma in the production of factor concentrates. In fact, BAXTER HEALTHCARE, unbeknownst to the FDA, continued to use prison plasma in factor concentrate production through October 1983. (BAXTER HEALTHCARE memorandum dated October 20, 1983.)

PARAGRAPH NO. 74 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

75. On January 5, 1983, an AIDS meeting was held at Children's Orthopedic Hospital in Los Angeles, California, the largest hemophilia treatment center in the United States. Representatives of four Defendants were present at the meeting with treaters and patients. The purpose of the meeting was to have Defendants' representatives answer patients' questions about AIDS transmission through factor concentrates. A patient asked representatives from CUTTER, ALPHA, ARMOUR and BAXTER the following question: "Is the plasma from homosexuals, prisoners, Haitians or other high risk persons being used in the manufacture of concentrates?" No Defendants admitted targeting or using plasma from homosexuals, prisoners or inner city IV drug abusers. Dr. Goodman from BAXTER HEALTHCARE answered regarding BAXTER HEALTHCARE'S use of known homosexuals as follows: "We are changing the nature of questions to homosexuals to the best of our ability." CUTTER'S responsible head, Stephen Ojala, an ALPHA representative, and ARMOUR'S Karl Hansen made no response to the question. This partial and misleading response amounted to concealment of the true risk created

by the use of known homosexuals, IV drug abusers and prisoners in the manufacture of factor concentrates.

PARAGRAPH NO. 75 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

76. At the January 5, 1983 meeting, and in the presence of the patients, one of the treating physicians, Dr. Kasper, asked CUTTER'S Stephen Ojala: "These [plasma] centers seem to be in rundown centers of town. Is there a move to move them to rural towns?" Ojala answered: "Many of the centers are in smaller communities and in towns such as Ypsilanti, Seattle, Clayton, NC., and San Diego. We do not have centers in L.A. or San Francisco." This answer was misleading because Ojala failed to state that CUTTER'S largest and first plasma center was located at Arizona State Penitentiary. CUTTER also had a center at the Las Vegas Prison. Ojala and CUTTER were well aware of the CDC's and FDA's concern over use of prison plasma, due to homosexual practices and drug abuse in the prison donor population. Many of CUTTER's centers were in inner city areas frequented by IV drug abusers, such as downtown Oakland, California. CUTTER had also used plasma from centers which targeted known homosexuals. In August 1982, CUTTER quarantined plasma from the Valley Medical Center, a center which targeted known homosexuals, because a donor was hospitalized with full blown AIDS. The plasma was intended for Factor IX and HBIG production, but was not used because it had thawed on the way to the processing plant. Upon receiving a report of this incident from CUTTER, the FDA indicated a recall might have been necessary if the plasma had been incorporated into factor concentrate final product. Ojala omitted any mention of these facts and circumstances in his response to Dr. Kasper regarding the location of their plasma centers. (CUTTER memorandum dated January 5, 1983.)

PARAGRAPH NO. 76 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required.

77. On January 14, 1983, Dr. Michael Rodell and the other responsible heads from Defendants attended a meeting of the National Hemophilia Foundation ("NHF"). The purpose of the meeting was to have Defendants explain to the NHF what steps they were prepared to take to safeguard the plasma supply from potential AIDS transmitters. Defendants were very concerned that the NHF would insist on a recommendation that HBc testing be implemented, consistent with the CDC recommendation 10 days earlier. BAXTER HEALTHCARE, under Rodell's supervision, had already conducted a survey of several of their donor centers to determine how many donors they would lose if the test were implemented. BAXTER HEALTHCARE had decided that up to 16% of their donors would not pass the test. Further, BAXTER

HEALTHCARE'S high titered immunoglobulin donors would be eliminated. In order to defer an NHF recommendation that HBc testing be used, Rodell told NHF officials that surrogate testing was in the "R and D," or "Research and Development," stage currently. Rodell concealed the fact that the CDC had strongly recommended use of the HBc Antibody test as a screening device for donors at high risk for AIDS transmission. The HBc Antibody test was not in the "R and D" stage, and was suitable for use as a screening device for high risk AIDS and Hepatitis C donors. In fact, the HBc test had been approved in 1979 by the FDA as a diagnostic test to be used to ascertain a history of previous hepatitis B infection, and as a screening device for blood and plasma donors. The test had the capability of identifying all donors with a history of viral hepatitis. Donors with a hepatitis history were specifically prohibited pursuant to the federal regulations (21 C.F.R. § 640.63). Rodell acknowledged that implementation of the HBc test would eliminate high titered immunoglobulin donors, but failed to disclose that opposition to use of the test was based on economic rather than safety concerns.

PARAGRAPH NO. 77 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that on January 14, 1983 representatives from various government agencies such as the FDA and CDC, representatives of various voluntary blood agencies, and representatives from the fractionation industry attended a meeting of the National Hemophilia Foundation. Baxter further admits only that it seriously considered the possibility of using HBc testing and that Baxter did perform an informal survey regarding HBc testing. The remaining factual allegations directed to Baxter are denied. By way of further answer, Baxter specifically denies that the CDC ever recommended HBc testing and specifically denies that HBc testing was ever licensed for any use other than diagnostic purposes. In fact, after 1983 the FDA explicitly confirmed that HBc testing was not to be used for plasma screening.

78. At the January 14, 1983 meeting, ALPHA, CUTTER and BAXTER concealed their advertising in publications distributed among urban homosexuals, for the specific purpose of attracting them to plasma centers which supplied high titered plasma to the Defendants. CUTTER and ALPHA concealed their extensive use of prison plasma, and BAXTER discussed plans to phase out prison plasma during the coming year. However, none of the Defendants revealed their "gentlemen's agreement" with the FDA to discontinue use of these plasma sources immediately. (CUTTER Memorandum dated January 17, 1983.)

PARAGRAPH NO. 78 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that it openly discussed and thus did not conceal its plans to phase out prison plasma during the coming year. The remaining factual allegations directed to Baxter, if any, are denied.

79. On or about December 15, 1983, Rodell, then the head of ARMOUR, told members of the federal Blood Product Advisory Committee (BPAC) and FDA officials that the Defendants wanted a three month deferral in implementation of any recommendations by the BPAC or FDA that HBc testing be required for plasma donors. Rodell told the FDA that the purpose of the deferral was to prepare a response to the proposed recommendation. In fact, the Defendants had agreed to seek the three month hiatus as a "delaying tactic" against implementing the test, and the request for a deferral was made in bad faith. (CUTTER memorandum dated December 13, 1983.)

PARAGRAPH NO. 79 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and thus no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that at a meeting on or about December 15, 1983, Michael Rodell, an employee of Armour, proposed to BPAC and certain members of the FDA, the creation of a Task Force to evaluate the utility of HBc testing and provide additional information in three months. Baxter specifically denies that this was a delaying tactic and further denies that the request for the establishment of a Task Force was made in bad faith. The remaining factual allegations directed to Baxter, if any, are denied.

80. It was strongly suggested by the CDC on July 27, 1982, that AIDS had a viral etiology similar to Hepatitis B because of the risk groups involved. These risk groups comprised a substantial portion of CUTTER'S plasma donor sources. CUTTER took no meaningful action to screen out donors at the highest risk for AIDS and Hepatitis C transmission at any time during the epidemic. In fact, they continued to market products containing plasma from these groups throughout 1982, 1983 and 1984 worldwide. Even more egregiously, CUTTER and other

Defendants continued to market high risk non-heat treated factor concentrate abroad after ceasing sales of such product in the United States in favor of vastly safer heat treated product.

PARAGRAPH NO. 80 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. All factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

81. Defendants, jointly and individually, fraudulently misrepresented the risk of AIDS and Hepatitis C due to factor concentrates, failed to disclose accurate warnings of the risk to Plaintiffs, Plaintiffs' Decedent or his physicians, and fraudulently purported to be doing "everything possible" to improve safety, when in fact Defendants maximized the risk by recruiting high risk donors and by resisting and obstructing HBc testing, heat treatment, and other measures that would truly have reduced the risk.

PARAGRAPH NO. 81 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. Baxter specifically denies that it engaged in any fraudulent activities, failed to disclose accurate warnings or recruited high risk donors. All remaining factual allegations directed to Baxter, if any, are denied.

H. Answer to Allegations Regarding Federal Regulations

82. Blood derivatives such as Factor VIII and IX are prescription biologicals subject to federal regulation as both "biological products" and "drugs." Public Health Service Act, "Regulation of Biological Products," 42 U.S.C. § 262; Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*.

(a) 21 U.S.C. § 331 (b) prohibited "adulteration or misbranding of any... drug, . . ."

(b) 21 U.S.C. § 351 (a)(2)(B) provided that "[a] drug. . . shall be deemed to be adulterated. . . if. . . the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good

manufacturing practice to assure that such drug meets the requirements of this chapter as to safety. . . ."

(c) 21 U.S.C. § 352 provided that "[a] drug…shall be deemed to be misbranded . . . if its labeling is false or misleading in any particular."

(d) 21 U.S.C. § 352(f)(2) provided that a drug shall be deemed to be "misbranded" unless its labeling bears "adequate warnings against use . . . where its use may be dangerous to health."

(e) 21 U.S.C. § 352(n) provided that a drug shall be deemed to be "misbranded" unless the labeling included information concerning side effects and contraindications as required in federal regulations.

(f) 21 U.S.C. § 321 (n) provided that if an article is alleged to be misbranded because the labeling or advertising is misleading, then the determination of whether the labeling or advertising is misleading shall take into account "not only representations made or suggested" by affirmative statements, "but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use" of the drug.

PARAGRAPH NO. 82 ANSWER: The allegations of this paragraph, including all of its subparts, constitute legal conclusions and therefore no response is required. Further, this paragraph, including its subparts, purports to quote provisions of the United States Code. Baxter denies any quotations, or portions thereof, which are not in conformity with the exact language of the referenced statute and, in any event, denies Plaintiffs' characterization of such language.

83. At all times material to this Complaint, 21 C.F.R. § 201.57(e) provided as follows, with respect to information to be provided with the sale of Defendants' products:

> Warnings: Under this section heading, the labeling shall describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association with a drug; a causal relationship need not have been proved.

84. At all times material to this Complaint, 21 C.F.R. § 200.5 provided as follows:

> Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians

> and others responsible for patient care. In the public interest, such mail shall be distinctive in appearance so that it will be promptly recognized and read.

85. At all times material to this Complaint, Part 606 of 21 C.F.R. set forth "Current Good Manufacturing Practices" for biological products generally, and 21 C.F.R. § 640, et seq., set forth additional good manufacturing practices for blood and plasma biologicals.

86. At all times material to this Complaint, 21 C.F .R. § 606. 140(a) provided:

> Laboratory control procedures shall include: The establishment of scientifically sound and appropriate specifications, standards and test procedures to assure that blood and blood components are safe, pure, potent and effective.

87. At all times material to this Complaint, 21 C.F .R. § 640.60 defined "Source Plasma (1-luman)" as

> the fluid portion of human blood which has been stabilized against clotting, collected by plasmapheresis, and is intended as source material for further manufacture into blood derivatives (a portion of pooled plasma separable by chemical means) intended for injection.

88. At all times material to this Complaint, 21 C.F.R. § 640.63(c), entitled "Qualification of Donor," provided as follows with respect to donors of source plasma:

> Donors shall be in good health on the day of donation, as indicated in part by: . . . (9) freedom from any disease, other than malaria, transmissible by blood transfusion, in so far as can he determined by history and examination indicated in this section; (10) freedom of the arms and forearms from skin punctures or scars indicative of addiction to self-injected narcotics; (11) freedom from a history of viral hepatitis; (12) freedom from a history of close contact within six months of donation with an individual having viral hepatitis; . . . .

Further, 21 C.F.R. § 640.63(a) provided that the method of determining "suitability of a donor" included "tests" as well as the taking of a history and physical examination.

89. At all times material to this Complaint, 21 C.F.R. § 606.140 provided as follows:

> Laboratory control procedures shall include: (a) The establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that blood and blood components are safe, pure, potent and effective.

PARAGRAPH NOS. 83-89 ANSWER: The allegations of these paragraphs constitute legal conclusions and therefore no response is required. Further, these paragraphs purport to quote provisions of the Code of Federal Regulations. Baxter denies any quotations, or portions thereof,

which are out of conformity with the exact language of the referenced regulation. Moreover, Baxter is without knowledge or information sufficient to form a belief as to what times Plaintiffs believe are "material to this Complaint" and therefore denies the allegations of these paragraphs on that basis and, in any event, Baxter denies Plaintiffs' characterization of such language.

90. The foregoing statutes and regulations are evidence of the standard of care Defendants should have employed in the manufacture and sale of Factor VIII and Factor IX. Defendants violated the foregoing regulations and/or failed to comply with applicable standards of care by: (a) marketing "adulterated" products that were unsafe as a result of failure to comply with "Current Good Manufacturing Practice"; (b) marketing "misbranded" products that were misleading and failed to disclose or warn of health dangers; (c) failing to warn of serious adverse reactions and potential safety hazards as soon as there was reasonable evidence of an association with the product; (d) failing to exclude intravenous drug users who were unsuitable donors; (e) failing to exclude donors with a history of viral Hepatitis who were unsuitable donors; (f) affirmatively seeking out unsuitable donors known to have viral Hepatitis antibodies, as well as prison populations known to include substantial numbers of intravenous drug users, for inclusion of their plasma in the pools used to make Factor VIII and Factor IX; (g) failing to disclose their use of dangerous donors; and (h) failing to use appropriate tests and/or procedures to assure the products were safe.

PARAGRAPH NO. 90 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically states that it at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

I. Answer to Allegations Regarding Conspiracy, Concert of Action and Group Liability

91. Defendants, and each of them, acted in concert and participated in a conscious and deliberate conspiracy to act negligently, fraudulently and with willful and wanton disregard for the rights and safety of blood product users, in connection with the manufacture of Factor VIII and IX blood products and the collection of constituent plasma.

PARAGRAPH NO. 91 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

92. Defendants herein tacitly and explicitly agreed to avoid upgrading industry standards. For example, the technology to virally inactivate factor concentrates existed in the early 1970's but was not seriously investigated by any of the Defendants until the early 1980s, despite its effective use in Europe. Use of the HBc antibody test to eliminate Hepatitis B carrier donors, and to identify donors with a history of viral Hepatitis, was known science by 1978. The HBc test was reported to be an effective surrogate test for both AIDS transmission and NANB Hepatitis carriers by 1982, yet no Defendant implemented this test until April 1984.

PARAGRAPH NO. 92 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

93. Defendants used donors from predominantly homosexual donor centers, prisons, and inner city areas where the risk of IV drug abuse was high. After July 1982, when the results of this conduct culminated in reports of fatal immune suppression in three people with hemophilia who infused the product, this concert of action took on a more overt, active form.

PARAGRAPH NO. 93 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

94. By December 1982, the FDA demanded that Defendants stop using prisoners, donors from high risk areas for hepatitis and AIDS transmission, and known homosexuals. Rather than use good faith efforts to comply with the FDA requests, Defendants collectively argued for a far less onerous and less effective donor screening program. They jointly proposed a system comprised of educating the donor by posting a placard in the donor center stating who the risk groups for AIDS transmission were, and advising the donor that he would be deferred if he acknowledged he was a member of one of those groups. Later, he would be required to fill out a questionnaire in private. If he checked the box indicating he was in a high risk group, he would be permanently deferred.

PARAGRAPH NO. 94 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter specifically admits that it used good faith efforts to institute donor screening measures, including the use of self-exclusion questionnaires early in the AIDS epidemic. Baxter specifically denies any purported implication that there was anything wrong with educating donors about the new and emerging condition which came to be known as AIDS and requesting donors to exclude themselves from donating plasma, if appropriate. HIV, the virus that causes AIDS, was not even identified until well after December 1982 and no test to detect HIV in plasma was commercially available until mid-1985. The remaining factual allegations directed to Baxter, if any, are denied.

95. At a January 6, 1983 meeting of Defendants' trade association, the Biological Section of the Pharmaceutical Manufacturer's Association ("PMA"), Defendants agreed not to implement highly effective HBc donor screening, instead selecting ineffective donor questionnaires that did little to screen out donors at high risk for AIDS transmission. Defendants further agreed to keep each other informed as to what the other was doing in order that a low standard of care was maintained. HBc testing had been strongly suggested by the CDC at the January 4, 1983 Public Health Service ("PHS") meeting. On January 14, 1983, Defendants acted jointly to persuade the National Hemophilia Foundation ("NHF") not to advocate surrogate testing for AIDS and Hepatitis C through implementation of the HBc test. Defendants persuaded the NHF that use of the HBc test was in the "R and D" stage and not practical to implement at that time.

PARAGRAPH NO. 95 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that it participated in a PMA meeting in January 1983 at which the issue of surrogate testing (HBc screening) was considered. Baxter specifically denies that HBc screening was "highly effective" at screening donors for AIDS. Baxter further states that HBc screening was not

approved by the FDA as a surrogate test for AIDS at that time, nor has it ever been approved for that purpose. The remaining factual allegations directed to Baxter, if any, are denied.

96. Defendants jointly agreed to oppose recall of the products beginning at the January 6, 1983 meeting at the Pharmaceutical Manufacturers' Association ("PMA"). Beginning with this meeting and continuing through at least July 19, 1983, Defendants met at various times to prepare a strategy to prevent the FDA from advocating a far-reaching recall of factor concentrate products. Defendants knew that due to their high risk donor populations, and their combining of these donors in pools of 5,000 to 40,000, that their products were contaminated with the AIDS agent. Nevertheless, Defendants acted in concert to lobby the FDA, to get the FDA to issue recommendations to limit recalls to circumstances in which an identified donor had died of AIDS within a specified time after the pooling of that donor's plasma. Defendants were well aware that plasma from contaminated asymptomatic donors were mixed in the plasma pools and contaminated virtually all lots. Defendants were successful in deferring any FDA Blood Products Advisory Committee ("BPAC") recommendation for a general recall of the product at the July 19, 1983 BPAC meeting. This joint action allowed the defendants to avoid ever recalling any product except when a donor died of AIDS.

PARAGRAPH NO. 96 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

97. Defendants conducted a meeting on or about January 6, 1983 at the PMA, a major purpose of which was to decide on a unified strategy to deal with increasing knowledge of risk of AIDS. At the meeting Defendants agreed to postpone submitting any request to the FDA for permission to amend their warning labels or package inserts. They further agreed not to apply to the FDA for warnings enhancements until the other three companies agreed to make application for warning enhancements and to make the warnings similar in content. At the time of the meeting, Defendants had been informed by various reliable health authorities, including the PHS, that there was evidence of an association of risk between factor concentrate use and the transmission of AIDS.

PARAGRAPH NO. 97 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits

that there was a PMA Meeting in January 1983 at which concerns regarding an emerging condition which came to be known as AIDS were discussed by concerned members of the industry. Baxter further admits that by the date of the PMA meeting, it was aware of speculation that this emerging disease might in some unknown manner be related to blood or blood based therapies. Baxter denies the implication that there was anything improper about talking with other members of its industry regarding issues of mutual concern. The remaining factual allegations directed to Baxter, if any, are denied.

98. On December 13, 1983, Stephen Ojala, CUTTER's responsible head, documented by written memorandum that Defendants met and jointly agreed to propose a "study" of the HBc surrogate screening test, as a "delaying tactic" to avoid implementing the HBc test.

PARAGRAPH NO. 98 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that in December 1983, certain representatives of the plasma industry, BPAC and the FDA were present at a meeting where the creation of a Task Force to evaluate and study the utility of HBc testing was proposed. Baxter specifically denies any suggestion that the proposed evaluation was intended to be a delaying tactic. By way of further response, Baxter states that to the extent that the allegations of this paragraph purport to rely on a document prepared by an individual who is or was not an employee of Baxter, Baxter denies the accuracy of such document. The remaining factual allegations directed to Baxter, if any, are denied.

99. Thereafter, at various times throughout 1983-1985, Defendants attended meetings or otherwise communicated to assure joint efforts to avoid recalling product; to avoid warning patients of the true risk; to market product when sales dropped due to information in the lay press related to AIDS transmission through factor concentrates; to avoid recall of non-heat-treated product after heat-treated products were available; to avoid implementation of the HBc test; and to coordinate a joint legal defense plan in anticipation of litigation from patients afflicted by

AIDS through use of the products. Defendants also operated through trade organizations, such as ABRA and PMA, to issue public statements minimizing the risks of AIDS and Hepatitis C and overpromoting the benefits of factor concentrate, to carry out the above-mentioned goals of all Defendants.

PARAGRAPH NO. 99 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits that it was a member of trade associations such as ABRA and PMA and, as is typical of members of many industries, it sometimes communicated with others in the same field through such trade groups. Baxter specifically denies the implication of this paragraph that there is something improper about belonging to a trade group. The remaining factual allegations directed to Baxter, if any, are denied.

100. All of the Defendants likely to have caused the harms to Plaintiffs are parties to this lawsuit and properly before the court.

PARAGRAPH NO. 100 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

101. The conduct of each and all of the Defendants, with respect to their Factor VIII and Factor IX products and related plasma collection methods, was tortious.

PARAGRAPH NO. 101 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

102. The harm which has been caused to Plaintiffs resulted from the conduct of one, or various combinations of the Defendants, and, through no fault of the Plaintiffs, there may be uncertainty as to which one or combination of Defendants caused the harm.

PARAGRAPH NO. 102 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

103. The burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by the Plaintiffs.

PARAGRAPH NO. 103 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

104. AHF was manufactured using the same fractionation method by all Defendants. As such, during the relevant years from 1975 until 1985, factor concentrates were a fungible product, and physicians prescribed the products interchangeably without regards to brand names of the drugs.

PARAGRAPH NO. 104 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. Baxter denies that its AHF was "manufactured" or that it was "fungible." Baxter's AHF was processed in accordance with Baxter's own proprietary procedures specifically approved and licensed by the Food and Drug Administration. Moreover, no two "AHF" therapies were the same and although some hemophiliacs could successfully use more than one brand of AHF, it was not uncommon for physicians to prescribe specific brands for specific hemophiliacs for whom certain therapies provided a better therapeutic outcome. The remaining factual allegations directed to Baxter, if any, are denied.

105. The factor concentrates manufactured by Defendants from 1975 until 1985 contained the same design flaws. They were all manufactured from paid donor plasma, which was at highest risk for Hepatitis B, Hepatitis C, and HIV viral transmission. In addition, the factor concentrate was made from large pools consisting of 5,000 to 40,000 paid donors, which further magnified the risk of viral transmission.

PARAGRAPH NO. 105 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. To the extent that these allegations are factual and directed to Baxter, Baxter admits only that it processed its factor concentrates from the pooled plasma of multiple donors. The remaining factual allegations directed to Baxter, if any, are denied.

106. None of the factor concentrate was virally inactivated during this time period. Therefore, all of the AHF carried a significant risk of viral transmission. In addition, all of Defendants' factor concentrate products were similarly misbranded. All of the products failed to warn of the known risks enumerated in this complaint.

PARAGRAPH NO. 106 ANSWER: To the extent that the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further response Baxter states that to the extent there were any risks associated with the use of factor concentrate about which Baxter knew or should have known and which gave rise to a duty to warn, Baxter at all times discharged such duty through appropriate and adequate warnings to physicians in accordance with applicable statutes and regulations and the existing state of medical and scientific knowledge.

V. ANSWER TO ALLEGATIONS REGARDING TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

107. Any and all potentially applicable statutes of limitations have been tolled by Defendants' affirmative and intentional acts of fraudulent conduct, concealment, and misrepresentation, alleged above, which estop Defendants from asserting statutes of limitation. Such acts include but are not limited to intentionally covering up and refusing to disclose use of high risk plasma; sale of products abroad known to be contaminated; suppressing and subverting medical and scientific research; and failing to disclose and suppressing information concerning the risks of HIV and HCV transmission from Defendants' contaminated factor concentrate. For example, while the spread of AIDS in homosexuals and IV drug users became known to the FDA and the public, only Defendants knew that these very populations were the donors Defendants were targeting to obtain plasma for their factor concentrate products.

PARAGRAPH NO. 107 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies any acts of fraudulent conduct, concealment or misrepresentation.

108. Defendants are estopped from relying on any statutes of limitation because of their fraudulent concealment and misrepresentation alleged above. Defendants were under a duty to disclose the risks of HIV and HCV transmission from their contaminated factor concentrate because this is nonpublic information over which they had exclusive control, because Defendants knew this information was not readily available to people with hemophilia like Plaintiffs' Decedent, and because this information was relevant to such people in deciding whether to use Defendants' factor concentrate.

PARAGRAPH NO. 108 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. By way of further answer, the remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies any acts of fraudulent conduct, concealment or misrepresentation. Baxter further denies that it owed a duty to act in any manner with regard to the processing of factor concentrates other than the manner in which it acted.

109. Until very recently, Plaintiffs had no knowledge that Defendants were engaged in much of the wrongdoing alleged herein. Because of the fraudulent and active concealment of the wrongdoing by Defendants, including but not limited to deliberate efforts which continue to this day-to give Plaintiffs the materially false impression that Defendants undertook all feasible safety precautions to reduce the risk of HIV and HCV transmission from their contaminated factor concentrate, Plaintiffs could not reasonably have discovered the wrongdoing any time prior to this time, nor could Plaintiffs have, as a practical matter, taken legally effective action given the unavailability, until very recently, of internal memoranda and other documents (as generally described herein) as evidence in support of Plaintiffs' claims. Defendants still refuse to admit and continue to conceal their wrongdoing, and therefore Defendants' acts of fraudulent concealment and misrepresentation continue through the present time.

PARAGRAPH NO. 109 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. By way of further answer, Baxter specifically denies any acts of fraudulent conduct, concealment or misrepresentation. Baxter further denies that Plaintiffs suffered any injuries as a result of any wrongful acts or omissions by Baxter.

VI. ANSWER TO ALLEGATIONS REGARDING CLAIMS FOR RELIEF

Answer to Plaintiffs' Wrongful Death Allegations

110. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

PARAGRAPH NO. 110 ANSWER: Baxter incorporates by reference its responses to all preceding paragraphs as if fully set forth herein and further answers as follows:

111. Defendants marketed their Factor VIII and/or Factor IX blood products to and for the benefit of Plaintiffs and Plaintiffs' Decedent, and knew or had reason to know of the defects in their Factor VIII and/or Factor IX blood products, and that Plaintiffs and Plaintiffs' Decedent would use the blood products.

PARAGRAPH NO. 111 ANSWER: To the extent the allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, no response is required from Baxter. The remaining factual allegations directed to Baxter, if any, are denied.

112. Defendants owed Plaintiffs and Plaintiffs' Decedent duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge, and to produce the blood factor concentrate products in as safe a manner and condition as possible.

PARAGRAPH NO. 112 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter at all times acted with due care, complied with applicable statutes and regulations, and acted in accordance with the existing state of medical and scientific knowledge.

113. Specific defects, as specified above in this Complaint, in the blood products, rendered them defective and unreasonably dangerous.

PARAGRAPH NO. 113 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. Baxter incorporates herein by reference its responses to all above paragraphs alleging specific defects as if set forth herein in their entirety.

114. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiffs' Decedent. Such breach exhibited a reckless disregard for the safety of others and willful and wanton conduct.

115. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Decedent died on or about March 31, 2007.

116. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Plaintiffs, individually and as representatives of Decedent, have been injured and have incurred damages, including but not limited to medical and hospital expenses in the past, past physical and mental pain and suffering, and have suffered loss of financial support, goods and services, consortium and the loss of familial and emotional love and support.

PARAGRAPH NOS. 114-116 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. Baxter incorporates herein by reference its responses to all foregoing and subsequent paragraphs alleging "conduct," as if set forth herein in their entirety. Baxter specifically denies

that its conduct was reckless, willful or wanton and denies all remaining factual allegations, if any.

117. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

PARAGRAPH NO. 117 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied.

118. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs and Plaintiffs' Decedent and was such as warrants an award of punitive damages.

PARAGRAPH NO. 118 ANSWER: The allegations of this paragraph constitute legal conclusions and/or are directed to parties other than Baxter, and therefore no response is required. The remaining factual allegations directed to Baxter, if any, are denied. Baxter specifically denies that its conduct was malicious, intentional, outrageous, willful or wanton or that any Plaintiff or Plaintiff's Decedent were injured or suffered damages as a result of a wrongful act or omission by Baxter.

WHEREFORE, Baxter Healthcare Corporation having fully answered, requests that this Court enter a judgment in its favor and against Plaintiffs, and award Baxter its costs and expenses, including attorneys' fees in this matter, and grant such other relief as the Court may deem just and proper.

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails, in whole or in part, to state a claim against Baxter upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs, if any, were caused by the negligence, fault, or other culpable conduct of persons other than Baxter and over whom Baxter had no control and for which matters Baxter bears no legal responsibility.

THIRD AFFIRMATIVE DEFENSE

At all relevant times, Baxter acted in conformity with the existing state of medical and scientific knowledge, common and accepted procedure in the medical field, and state of the art in the processing and distribution of factor concentrates.

FOURTH AFFIRMATIVE DEFENSE

The state of scientific and technical knowledge at the time when the therapy was put into circulation was not such as to enable Baxter to know the existence of the alleged defect, if any, or discover it.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitation and/or statutes of repose.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the learned intermediary doctrine.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrines of laches, waiver and/or estoppel.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by doctrines concerning unavoidably unsafe therapeutics under the Restatement (Second) of Torts: Product Liability §402A and comments thereto and/or Restatement (Third) of Torts: Products Liability §6 and comments thereto.

NINTH AFFIRMATIVE DEFENSE

Some or all of Plaintiffs' claims are barred or subject to reduction by the doctrines of contributory negligence or comparative fault. Accordingly, any recovery must be diminished to the extent of a finding of contributory negligence and/or comparative fault against them.

TENTH AFFIRMATIVE DEFENSE

Plaintiffs' Decedent was warned of and/or assumed the risk, if any, related to the use of factor concentrates.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' Decedent, knowing the nature and properties of factor concentrates, consented to their use, and accordingly Baxter cannot be held liable.

TWELFTH AFFIRMATIVE DEFENSE

Baxter's factor concentrate is a prescription biologic which has been licensed and approved under 42 U.S.C. Section 262 and the regulations issued thereunder. At all relevant times, Baxter's conduct was in compliance with the aforementioned statute and all other applicable federal statutes and regulations, including but not limited to the federal Food, Drug, and Cosmetic Act which preempt and bar the Plaintiffs' claims, in whole or in part, by operation of the Supremacy Clause of the United States Constitution.

THIRTEENTH AFFIRMATIVE DEFENSE

At all relevant times, Baxter's conduct was in compliance with applicable foreign regulations issued by the applicable foreign authorities, and Plaintiffs' recovery against Baxter is therefore barred.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to join parties necessary and/or indispensable to a just adjudication of this lawsuit.

FIFTEENTH AFFIRMATIVE DEFENSE

The alleged injuries of Plaintiffs were the result of unavoidable circumstances, which could not have been prevented by anyone.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries or damages, if any, were proximately caused by an intervening or superseding cause, and Plaintiffs' recovery against Baxter is therefore barred.

SEVENTEENTH AFFIRMATIVE DEFENSE

The Complaint fails to allege any cause of action which would entitle Plaintiffs to exemplary or punitive damages under the applicable and/or governing law.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' demands for exemplary and punitive damages are barred because any award of such damages would violate the due process clauses of the Fifth and Fourteenth Amendments to the United States Constitution by allowing standardless discretion to the jury to determine punishment and by depriving Baxter of prior notice of the consequences of its alleged acts.

NINETEENTH AFFIRMATIVE DEFENSE

With respect to Plaintiffs' demand for punitive damages, Baxter specifically incorporates by reference all standards of limitations regarding the determination and enforceability of punitive damages awards which arose in the decisions of BMW of North America v. Gore, 517 U.S. 559 (1996), Cooper Industries, Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424 (2001), State Farm Mut. Automobile Ins. Co. v. Campbell, 538 U.S. 408 (2003), and Philip Morris USA v. Williams, 538 U.S. 408 (2007). To the extent Plaintiffs' demand for punitive damages is governed by foreign law, punitive damages are not available to Plaintiffs under applicable and/or governing law.

TWENTIETH AFFIRMATIVE DEFENSE

Punitive damages are a punishment, a quasi-criminal sanction for which Baxter has not been afforded the specific procedural safeguards prescribed in the Fifth and Sixth Amendments to the United States Constitution.

TWENTY-FIRST AFFIRMATIVE DEFENSE

The Complaint fails to allege a cause of action that would entitle Plaintiffs to attorneys' fees or costs.

TWENTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs have failed to give timely notice of their breach of warranty claims, if any, and therefore are precluded from recovery.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because they failed to mitigate damages.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs' claims rest upon any theory that would allow a finding of liability without requiring proof of causation, they violate Baxter's rights under the United States Constitution, the Constitution of the State of Illinois and such other laws as may be applicable.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, pursuant to the doctrine of primary jurisdiction; the FDA is charged with regulating biologics, including factor concentrates, and is specifically charged with determining the content of the warnings and labeling for biologics.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001).

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs attempt to seek equitable relief, they are not entitled to such relief because they have an adequate remedy at law.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Some of Plaintiffs' claims are barred in whole or in part by the First Amendment of the Constitution of the United States and/or the applicable Constitution or equivalent legal document of any state or foreign nation whose laws might be deemed controlling in this case.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Any recovery by Plaintiffs must be reduced or offset by amounts Plaintiffs have received or will receive from others for the same injuries claimed in this lawsuit.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because Baxter did not owe them any legal duty or, if Baxter did owe such a legal duty, it did not breach that duty.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Damages for losses claimed by Plaintiffs are limited by the California Medical Injury Compensation Reform Act ("MICRA") including but not limited to California Code Sections 3333.1 and 3333.2, or other similar applicable statutes placing a cap on liability.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Some of the Plaintiffs' alleged injuries or damages, if any, were the result of the misuse of factor concentrate.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by the blood shield statutes of Illinois, or by the blood shield statutes of such other jurisdictions as may be applicable.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred or should be reduced under the doctrine of avoidable consequences due to Plaintiffs' failure to mitigate damages.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries and losses, if any, were proximately caused by their own acts or omissions and their claims are therefore barred.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries and losses, if any, were proximately caused by Plaintiffs' Decedent's own failure to use factor concentrate in a reasonably foreseeable and intended manner, or in a manner consistent with the therapy's labeling and Plaintiffs' claims are therefore barred.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

If it is determined that a risk is inherent in factor concentrate, then such risk is outweighed by the benefits of factor concentrates.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs rely upon the doctrine of failure to warn, they have failed to state a claim upon which relief can be granted.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because there is no privity between Plaintiffs and Baxter.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' rights and claims against Baxter, if any, are barred in whole or in part by public policy considerations.

FORTY-FIRST AFFIRMATIVE DEFENSE

No implied warranties of fitness for a particular purpose, or for merchantability, existed with respect to any transaction alleged to have been entered by Baxter, or in the alternative, such warranty or cause of action based upon such warranty was waived by Plaintiffs.

FORTY-SECOND AFFIRMATIVE DEFENSE

Any condition in question alleged to have constituted a breach of implied warranties by Baxter was not a proximate cause of Plaintiffs' alleged injuries or damages.

FORTY-THIRD AFFIRMATIVE DEFENSE

Some or all of Plaintiffs' claims are barred, in whole or in part, by the doctrines of res judicata, and/or satisfaction and accord.

FORTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent they seek to impose liability retroactively for conduct that was not actionable at the time it occurred.

FORTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs and their counsel have vexatiously and unreasonably pursued this action and Baxter is therefore entitled to costs, expenses and attorneys' fees reasonably incurred because of such conduct.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrine of lis pendens based on the prior pending action filed by Eli Ashkenazi individually in Ashkenzi, et al. v. Bayer Corp. et al., 05-c-2793 (N.D. Ill.), filed on May 5, 2005.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by settlement of their claims.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims fail, in whole or in part, because of improper claim splitting.

FORTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent laws within their own country provide for financial compensation or assistance for Plaintiffs' alleged injuries.

FIFTIETH AFFIRMATIVE DEFENSE

Plaintiffs may not recover on the claims pleaded in the Complaint because the damages sought are too speculative and remote.

FIFTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims for relief, on their face and as applied, violate the Excessive Fines Clause of the United States Constitution, and/or the applicable Constitution or equivalent legal document of any state or foreign nation whose laws might be deemed controlling in this case.

FIFTY-SECOND AFFIRMATIVE DEFENSE

While denying at all times that factor concentrates processed by Baxter caused or contributed to the injuries and damages alleged in the Complaint, Baxter avers that Plaintiffs'

Decedent was warned or otherwise made aware of the alleged risks and further, that any such risks, to the extent they existed, were not beyond those that would have been contemplated by an ordinary user. Plaintiffs therefore, are barred from any recovery on the claims asserted.

FIFTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' fraud and misrepresentation claims cannot be sustained because Baxter did not have superior knowledge of material facts that were not also readily available to Plaintiffs and Plaintiffs have failed to plead such claims with particularity.

FIFTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' rights to compensation, if any, have already been adjudicated in their home country.

FIFTY-FIFTH AFFIRMATIVE DEFENSE

Any decision in this Court, in favor of the Plaintiffs, would violate legally and properly enacted provisions of the law in their home country.

FIFTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are not justiciable, as their adjudication would violate the Act of State Doctrine.

FIFTY-SEVENTH AFFIRMATIVE DEFENSE

This Court is neither a proper nor convenient forum for the just adjudication of Plaintiffs' claims.

FIFTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the law of the jurisdictions in which they reside and are, as such, barred in this Court by principles of comity.

FIFTY-NINTH AFFIRMATIVE DEFENSE

Any affirmative defenses pleaded by the other Defendants and not pleaded by Baxter are hereby incorporated herein to the extent they do not conflict with Baxter's affirmative defenses.

SIXTIETH AFFIRMATIVE DEFENSE

Baxter hereby gives notice that it intends to plead any affirmative defenses available to Baxter under the law of the country where Plaintiffs reside and hereby reserves the right to amend its Answer to assert such defenses.

SIXTY-FIRST AFFIRMATIVE DEFENSE

Baxter hereby gives notice that it intends to rely upon any other defense that may become available or appear during the discovery proceedings in this case and hereby reserves the right to amend its Answer to assert such defenses.

SIXTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims may fail due to lack of jurisdiction.

SIXTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are improperly joined and should be dismissed.

SIXTY-FOURTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs' claims involve or relate to witnesses and/or other evidence (documentary or otherwise) which lies beyond the subpoena power of this court, Plaintiffs'

claims and any award or judgment resulting from proceedings in this country constitute an unconstitutional violation of Defendants' rights to due process.

WHEREFORE, Baxter Healthcare Corporation having fully answered, requests that this Court enter a judgment in its favor and against Plaintiffs, and award Baxter its costs and expenses, including attorneys' fees in this matter, and grant such other relief as the Court may deem just and proper.

Dated: August 22, 2008

s/ RICHARD L. BERKMAN

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Attorney for Defendant
Baxter Healthcare Corporation

DEMAND FOR JURY TRIAL

Defendant Baxter Healthcare Corporation demands a trial by jury on all issues stated.

Dated: August 22, 2008

s/ RICHARD L. BERKMAN
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Attorney for Defendant
Baxter Healthcare Corporation

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of August, 2008, that I caused to be served a true and correct copy of Baxter Healthcare Corporation's Answer to Plaintiff's First Amended Complaint, Affirmative Defenses, and Demand for Jury Trial upon the following counsel of record pursuant to ECF as to Filing Users and by DHL delivery, postage prepaid, pursuant to Local Rule 5.5 as to any party who is not a Filing User or represented by a filing user:

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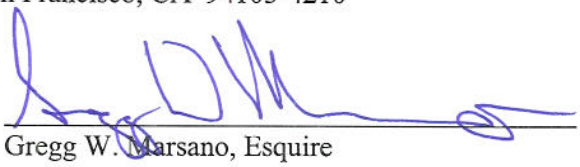

Gregg W. Marsano, Esquire